IO25344

Bayer CropScience

June 28, 2013

Document Processing Desk 6(a)(2)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

RE: 6(a)(2) Incidents Accumulated for the Month of May 2013

Dear Sir/Madam:

Reportable incidents accumulated for the month of May 2013 for Bayer CropScience and Bayer Environmental Science are attached.

Bayer CropScience
RTP
P. O. Box 12014
RTP, NC 27709
Tel. 919 549-2000

The information with this letter is being submitted to the EPA pursuant to the Agency's interpretation of requirements imposed on registrants by Section 6(a)(2) of FIFRA. This information does not necessarily constitute additional factual information regarding unreasonable adverse effects within the meaning of 6(a)(2). It is being submitted to enable the Agency to make its own assessment of the information.

If you have questions or concerns, please do not hesitate to contact me at any time.

Sincerely,

S. Gerret Van Duyn

Gerret Van Duyn
Compliance Manager
State Regulatory and Documentation Services
919-549-2914

CC: AE Coordinator, CA Department of Pesticide Regulation
Jeanine Broughel, NY Department of Environmental Conservation

/attachment

Personal privacy information I025344

-001

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area

Row 1 Administrative Data	Reporter Name [redacted]	Submission date. *6/28/13*	Contact person (if different than reporter)	Internal ID *1159738*
	Address [redacted]		Address	
	Phone # [redacted]		Phone #	
	Incident Status: *New*	Location and date of incident *Pittsburgh, PA* *USA* *04/29/2013*	Date registrant became aware of incident. *05/02/2013*	Was incident part of larger study? *No*

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) *72155-80*	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) ***Beta-Cyfluthrin, sodium o-phenylphenate***	A.I. (s)	A.I. (s)
	Product 1 name ***Home Pest plus Germ Killer Indoor & Outdoor Killer RTU (24 oz)***	Product 2 Name	Product 3 Name
	Exposed to concentrate prior to dilution? *No*	Exposed to concentrate prior to dilution?	Exposed to concentrate prior to dilution?
	Formulation ***Liquid***	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? *No* Intentional misuse? *No* Applicator certified? *UNK*	Incident site: (examples include home, yard, school, industrial, nursery/greenhouse, surface water, commercial turf, building/office, forest/ woods, agricultural (specify crop) right-of-way (rail, utility, highway)). ***Own Residence***	Situation (act of using product): (examples include mixing/loading, reentry, application, transportation, repair/ maintenance of application equipment, manufacturing/ formulating). ***See Incident Description Notes***
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff) ***See Incident Description Notes***		

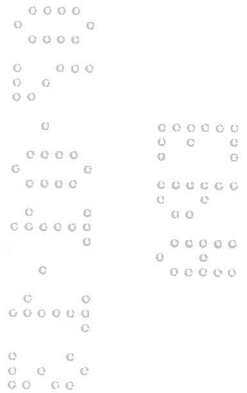
1a

Brief description of incident circumstances.

Dee, Tammy May 2 2013 12:36PM
Hx. Caller states his wife used the product in his home on 4/29/13 and states his wife developed a HA, nausea, and vomiting several hours after use. The caller states his wife went to her MD on 4/30/13 and she was sent to the ER for IVF's, and she was then discharged feeling much improved however the caller states she developed diarrhea and felt weak and she went back to the MD this AM and she is hospitalized now with elevated liver enzymes. The caller states his wife does not remember any specific exposure to the product, but he is wondering if the elevated liver enzymes could be related to product use.

A. We would not anticipate the persistent sxs noted or changes in liver enzymes with the unknown exposure described. Even if a small TTL was inadvertently ingested we may see slight self-limitng GI upset but would not anticipate persistency or change in liver values. Assured caller MD eval was warranted given sxs and rec. continued supportive care with MD as well as searching for other potential etiologies for sxs noted. Provided C#, please Cb prn as we are here 24/7. Alerted LT.
****
LeMaster, Steve Jun 3 2013 12:04PM
CB to initial caller - reports that wife was in the hospital for about 3-4 days. Was determined to be a 'severe stomach flu' and dehydration that had been the issue. Wife was unable to eat / drink for several days and felt to be the cause for the elevation of the liver enzymes. She is doing well today.

Appreciated the follow up call



2

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area

<table>
<tr><td>Demographic information:
Age: 47 Year(s) Sex: Female
Occupation (if relevant)
NA</td><td>Exposure route:
Unknown route</td><td>Was adverse effect result of suicide/homicide or attempted suicide/homicide?
No</td><td rowspan="2">Was protective clothing worn (specify)?
None Reported</td></tr>
<tr><td>If female, pregnant?
NO</td><td>Was exposure occupational?
Not indicated
If yes, days lost due to illness:
NA</td><td>Time between exposure and onset of symptoms:
8 hrs or less</td></tr>
<tr><td>Type of medical care sought: (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient).
ER/Hospital-admitted</td><td colspan="2" rowspan="3">List signs/symptoms/adverse effects
Gastrointestinal-Diarrhea
Gastrointestinal-Emesis/Vomiting
Heme/Hepatic-Unknown Liver Value Elevation
Miscellaneous-Dehydration
Neurological-Headache</td><td rowspan="3">If lab tests were performed, list test names and results (If available, submit reports)
None Reported</td></tr>
<tr><td>Exposure data: NA
Amount of pesticide: NA
Exposure duration: Acute < 8hrs
Patient weight: Unknown</td></tr>
<tr><td>Human severity category:
HC</td></tr>
<tr><td colspan="4">This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
1159738</td></tr>
</table>

3

Personal privacy information

- 002

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area

Row 1 Administrative Data	Reporter Name [redacted]	Submission date. ***6/28/13***	Contact person (if different than reporter)	Internal ID ***1160909***
	Address [redacted]		Address	
	Phone # [redacted]		Phone #	
	Incident Status: ***New***	Location and date of incident ***Albany, NY*** ***USA*** ***04/06/2013***	Date registrant became aware of incident. ***05/04/2013***	Was incident part of larger study? ***No***

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) ***72155-80***	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) ***Beta-Cyfluthrin, sodium o-phenylphenate***	A.I. (s)	A.I. (s)
	Product 1 name ***Home Pest plus Germ Killer Indoor & Outdoor Killer RTU (1 Gal)***	Product 2 Name	Product 3 Name
	Exposed to concentrate prior to dilution? ***No***	Exposed to concentrate prior to dilution?	Exposed to concentrate prior to dilution?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? ***Yes*** Intentional misuse? ***Yes*** Applicator certified? ***UNK***	Incident site: (examples include home, yard, school, industrial, nursery/greenhouse, surface water, commercial turf, building/office, forest/ woods, agricultural (specify crop) right-of-way (rail, utility, highway)). ***Own Residence***	Situation (act of using product): (examples include mixing/loading, reentry, application, transportation, repair/ maintenance of application equipment, manufacturing/ formulating). ***See Incident Description Notes***
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff) ***See Incident Description Notes***		

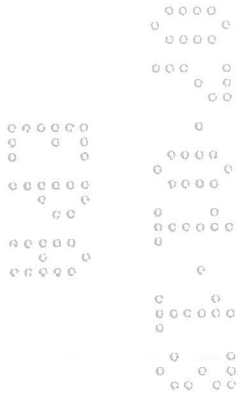
4

Brief description of incident circumstances.

Billings, Sharon May 4 2013 10:35AM
Hx: Caller reports he may have got product on his skin after applying it to couch and bed in his home for bed bugs about 4 weeks ago. Starting about 2 days later he developed a blister on his hand; subsequently he has developed red 'blood blisters' and a rash on his hands, arms, neck, and torso. He was also pruritic and had swelling in these areas. About 2 days later he went to the ED and was treated with oral antihistamine and injectable steroids. His sxs persisted and he returned to ED about 1 week later where he was administered a cream to apply dermally for mites. Sxs abated but persist.

A: Product contains insecticides in low concentrations. Although dermal contact may result in irritation the nature, severity, and persistence of sxs would not be anticipated with labeled use; recommend considering additional causes and continue to work with your health care provider for treatment of sxs. Bring product information with you and have your health care professional contact us using your case reference number if more information or consultation is needed. Gave case#, cb prn.

Notified LT



5

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area

<table>
<tr><td>Demographic information:
Age: 52 Year(s) Sex: Male
Occupation (if relevant)
NA</td><td>Exposure route:
Dermal</td><td>Was adverse effect result of suicide/homicide or attempted suicide/homicide?
No</td><td rowspan="2">Was protective clothing worn (specify)?
None Reported</td></tr>
<tr><td>If female, pregnant?
NA</td><td>Was exposure occupational?
Not indicated
If yes, days lost due to illness:
NA</td><td>Time between exposure and onset of symptoms:
3 days or less</td></tr>
<tr><td>Type of medical care sought: (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient).
ER/Hospital-treated & released</td><td colspan="2" rowspan="3">List signs/symptoms/adverse effects
Dermatological-Animal sting
Dermatological-Bullae/Blisters
Dermatological-Edema/Swelling
Dermatological-Hives/Welts
Dermatological-Pruritus (itching)
Dermatological-Rash</td><td rowspan="3">If lab tests were performed, list test names and results (If available, submit reports)
None Reported</td></tr>
<tr><td>Exposure data: NA
Amount of pesticide: NA
Exposure duration: Acute < 8hrs
Patient weight: Unknown</td></tr>
<tr><td>Human severity category:
HC</td></tr>
<tr><td colspan="4">This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)</td></tr>
<tr><td colspan="3"></td><td>Internal ID #
1160909</td></tr>
</table>

6

Personal privacy information

_ 003

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area

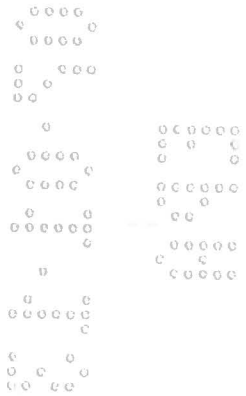
Row 1 Administrative Data	Reporter Name [redacted]	Submission date. *6/28/13*	Contact person (if different than reporter)	Internal ID *1165577*
	Address [redacted]		Address	
	Phone # [redacted]		Phone #	
	Incident Status: *New*	Location and date of incident *Diboll, TX* *USA* *Chronic: >24 <= 1 week*	Date registrant became aware of incident. *05/11/2013*	Was incident part of larger study? *No*
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) *72155-80*	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) ***Beta-Cyfluthrin, sodium o-phenylphenate***	A.I. (s)	A.I. (s)	
	Product 1 name ***Home Pest plus Germ Killer Indoor & Outdoor Killer RTU (1 Gal)***	Product 2 Name	Product 3 Name	
	Exposed to concentrate prior to dilution? ***Unknown***	Exposed to concentrate prior to dilution?	Exposed to concentrate prior to dilution?	
	Formulation	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? ***No*** Intentional misuse? ***No***	Incident site: (examples include home, yard, school, industrial, nursery/greenhouse, surface water, commercial turf, building/office, forest/ woods, agricultural (specify crop) right-of-way (rail, utility, highway)). ***Own Residence***	Situation (act of using product): (examples include mixing/loading, reentry, application, transportation, repair/ maintenance of application equipment, manufacturing/ formulating). ***See Incident Description Notes***	
	Applicator certified? ***UNK***			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff) ***See Incident Description Notes***			

7

Brief description of incident circumstances.

Buckingham, Amber May 11 2013 11:23PM
Hx. Caller states that she would like to know if this product could be the cause of her husbands sxs; V/D, fever, chills, and headache. Caller states that they used this product in the house on Wednesday May 8, 2013 sometime in the afternoon. Caller states that the next morning, her husband woke up with those sxs. Caller states that her husband was only exposed to the product for about 5min and had initially experienced some coughing and respiratory irritation after being exposed to it. Caller states that her husband has gone to the doctor twice now, but did not think about this product being the reason for his illness until tonight. Caller states that the MD gave her husband a Rx for Bactrim and a Zpack.

A. The sx described does not fit the toxicological profile of this product. He would have to be exposed to this product for at least 4hrs at the highest concentration in a non ventilated area for there to be any signs of toxicity. If any new or unexpected symptoms develop, or if you have any other questions or concerns, please callback 24/7.



8

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area

Demographic information: Age: ***Adult (20-64 years)*** Sex: ***Male*** Occupation (if relevant) ***NA***	Exposure route: ***Inhalation/Respiratory***	Was adverse effect result of suicide/homicide or attempted suicide/homicide? ***No***	Was protective clothing worn (specify)? ***None Reported***
If female, pregnant? ***NA***	Was exposure occupational? ***Not indicated*** If yes, days lost due to illness: ***NA***	Time between exposure and onset of symptoms: ***24 hrs or less***	
Type of medical care sought: (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient). ***Private MD/DVM-treated & released***	List signs/symptoms/adverse effects ***Gastrointestinal-Diarrhea*** ***Gastrointestinal-Emesis/Vomiting*** ***Miscellaneous-Fever/hyperthermia*** ***Miscellaneous-Chills/Rigors***		If lab tests were performed, list test names and results (If available, submit reports) ***None Reported***
Exposure data: ***NA*** Amount of pesticide: ***NA*** Exposure duration: ***Chronic: >24 <= 1 week*** Patient weight: ***Unknown***			
Human severity category: ***HC***			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
1165577

9

Personal privacy information

-006

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area

Row 1 Administrative Data	Reporter Name [redacted]	Submission date. ***6/28/13***	Contact person (if different than reporter)	Internal ID ***1171454***
	Address [redacted]		Address	
	Phone # [redacted]		Phone #	
	Incident Status: ***New***	Location and date of incident ***Haines City, FL*** ***USA*** ***Chronic: >1 month <= 3 months***	Date registrant became aware of incident. ***05/21/2013***	Was incident part of larger study? ***No***

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) ***72155-80***	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) ***Beta-Cyfluthrin, sodium o-phenylphenate***	A.I. (s)	A.I. (s)
	Product 1 name ***Home Pest plus Germ Killer Indoor & Outdoor Killer RTU (1 Gal)***	Product 2 Name	Product 3 Name
	Exposed to concentrate prior to dilution? ***No***	Exposed to concentrate prior to dilution?	Exposed to concentrate prior to dilution?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? ***No*** Intentional misuse? ***No*** Applicator certified? ***UNK***	Incident site: (examples include home, yard, school, industrial, nursery/greenhouse, surface water, commercial turf, building/office, forest/ woods, agricultural (specify crop) right-of-way (rail, utility, highway)). ***Own Residence***	Situation (act of using product): (examples include mixing/loading, reentry, application, transportation, repair/ maintenance of application equipment, manufacturing/ formulating). ***See Incident Description Notes***
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff) ***See Incident Description Notes***		

16

Brief description of incident circumstances.

O'Rourke, Carrie May 21 2013 4:23PM
Hx. Caller states that he sprayed this product in their bedroom around the first of the year. Caller states that after 1 week after spraying the product his wife began to having coughing fits. His wife then gets headaches as a result from her coughing. Caller states they have taken her to many different doctors for her sxs and they do not have a specific answer for why. She is always given oral steroids and antibiotics which clears up her sxs for about a week to two weeks at at time.

A. This is not an anticipated reaction from the use of the product. Once the product is dry I would not anticipate any issues from the product. Rec. continuing care under MD for further treatment. Provided case #. Have MD call if they have any questions. If you have any other questions or concerns please callback 24/7.

17

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area

<table>
<tr><td>Demographic information:
Age: 75 Year(s) Sex: Female
Occupation (if relevant)
NA</td><td>Exposure route:
Unknown route</td><td>Was adverse effect result of suicide/homicide or attempted suicide/homicide?
No</td><td rowspan="2">Was protective clothing worn (specify)?
None Reported</td></tr>
<tr><td>If female, pregnant?
NO</td><td>Was exposure occupational?
Not indicated
If yes, days lost due to illness:
NA</td><td>Time between exposure and onset of symptoms:
1 week or less</td></tr>
<tr><td>Type of medical care sought: (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient).
Private MD/DVM-treated & released</td><td colspan="2" rowspan="3">List signs/symptoms/adverse effects
Neurological-Headache
Respiratory-Cough/choke</td><td rowspan="3">If lab tests were performed, list test names and results (If available, submit reports)
None Reported</td></tr>
<tr><td>Exposure data: NA
Amount of pesticide: NA
Exposure duration: Chronic: >1 month <= 3 months
Patient weight: Unknown</td></tr>
<tr><td>Human severity category:
HC</td></tr>
<tr><td colspan="4">This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
1171454</td></tr>
</table>

18